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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,795	06/21/2006	Kiyotaka Nakano	19672-003US1 RET/PCG-9009	4422
26161 7590 12/18/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER BRISTOL, LYNN ANNE	
			ART UNIT	PAPER NUMBER
			1643	
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			12/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,795	Applicant(s) NAKANO ET AL.	
	Examiner Lynn Bristol	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1-33 are all the pending claims for this application and subject to unity of invention analysis.
2. It is noted that Claims 19-23 are in improper form because a multiple dependent claim cannot depend from another multiple dependent claim under U.S. practice (MPEP § 608.01(n)). Applicants are requested to correct the claim dependency for these and any other claims that are improper multiply dependent.

Unity of Invention

3. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to anti-glypican 3 antibodies.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

A search of the heavy chain and light chain variable domain sequences in commercial protein sequence databases for the following anti-glypican 3 antibodies did not identify any art references teaching or suggesting the antibodies: GC33 (SEQ ID NO:62/73); M11F1 (SEQ ID NO: 26/48); M3B8 (SEQ ID NO:25/47); GC199 (SEQ ID NO: 60/71); GC202 (SEQ ID NO: 61/72); GC179 (SEQ ID NO: 63/74); GC194 (SEQ ID

NO: 64/75); M13B3 (SEQ ID NO:23/45); L9G11 (SEQ ID NO:32/54); MGB1 (SEQ ID NO: 28/50); M5B9 (SEQ ID NO: 30/52) and M10D2 (SEQ ID NO: 31/53).

As the technical features for antibodies is found to be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, the Examiner finds there to be a single inventive concept underlying the plurality of claimed inventions (for the first claimed product, its method of making and a method of using the product).

4. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, 21-23 and 28-33, drawn to an anti-glypican 3 antibody, a cell growth inhibitor comprising the antibody, and an anti-cancer agent comprising the antibody.

Group II, claim(s) 19 and 20, drawn to a polynucleotide encoding a heavy or light chain variable domain of an anti-glypican 3 antibody .

Group III, claim(s) 24-27, drawn to a peptide comprising residues 524-563, 537-563, 544-553 or 546-551 of glypican 3.

5. Three (3) different products are presented in Groups I-III. These three products do not share a common property or activity and do not share common core structures. None of the products is overlapping in its structure, its inherent biological properties nor

are the products interchangeable in use of one for the other. Thus the inventions of Groups I-III are patentably distinct.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER